

Clinical Laboratory Program

99 Chauncy Street, 2nd Floor, Boston, MA 02111
(617) 753-8439/8438 (617) 753-8240 - Fax

WAIVED HIV SPECIAL PROJECTS WAIVER APPLICATION**I. APPLICATION INFORMATION**

Name: _____

Address: _____
Street City State Zip code

Telephone: _____ Contact Person: _____

CLIA #: _____ Certificate Type: _____

II. SCREENING PROGRAM INFORMATION**A.. Facility or company which will provide final disposal of the holder's special medical waste:**

Name: _____

Address: _____
Street City State Zip code

Telephone: _____

B.) Licensed laboratory where specimens will be sent semi-annually to verify test accuracy:

Name: _____

Address: _____
Street City State Zip code

Telephone: _____ Contact Person: _____

C.) Licensed laboratory where specimens will be sent for confirmatory testing (if required):

Name: _____

Address: _____
Street City State Zip code

Telephone: _____ Contact Person: _____

III. TESTING LOCATION(S)

A.) Address (street, city) of Permanent Testing Location

Schedule of Operation

Days of Week

Time (Hours)

B.) Address of Off-Site Testing Locations

Schedule of Operation

Days of Week

Time (Hours)

C.) Personnel

Laboratory Director

Program Contact Person

Signature of Authorized Individual

Title:

Date:

Telephone:

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WAIVED HIV SPECIAL PROJECTS**REQUIRED DOCUMENTS**

- ☐ **Application for Clinical Laboratory Improvement Amendments of 1998 [CLIA] Certificate** - complete, sign, date and return
download CMS 116 form from website: <http://www.cms.hhs.gov/forms/>

OR

Copy of your current CLIA Certificate

- ☐ **“WAIVED” HIV Special Projects Waiver Application**- complete, sign, date and return
download from website

- ☐ **Training Program**
- § Copy of training program / material
 - § Ongoing competency protocol
 - § Training records for current testing personnel

- ☐ **Procedures**
- § HIV(waived) step by step testing procedure
 - § Confidentiality procedures
 - § Quality control procedure
 - § Confirmatory process - include copy of agreement with reference laboratory if confirmatory testing is not provided on-site
 - § Patient and testing personnel safety protocols

- ☐ **Counseling, Referrals and Test Integration**
- § Copies of pre and post test protocols
 - § Description of referral process
 - § Description of rapid test integration

Failure to provide this information in a timely manner will result in a delay in the processing of information required for the issuance of a Massachusetts Clinical Laboratory Special Waiver Approval.